Michelle A. Smith, Ph.D.
200 "C" Street, S.W., Room 4133
Washington, D.C. 20204

U.S. Food and Drug Administration
Center for Food Safety and Applied Nutrition

FDA / Department of Health and Human Services

RE: Docket Nos. 99D – 4488 and 99D - 4489

Michelle,

The following are some of my own personal comments on the sprouting industry, and my response regarding the recommended guidelines. Although my personal comments may not be relevant to the recommended guidelines, they are relevant to the state of the industry at the present time. Thank you in advance for any considerations that may be taken.

While there have been incidences of pathogenic outbreaks, and ultimately it is the reason for the recent guideline set forth for the sprouting industry, I view the problem much larger than just the outbreaks.

At the present time there are few sprout growers whose facility would pass as true food processing facilities, and fewer yet using any control points as Standard Operating Procedures to help prevent or eliminate any human pathogens from entering our food supply. As noted in the recommendations, seed production, seed producers, and seed distributors are also a problem that must be addressed.

There are some growers in business that should never have been granted a food-processing license by the local inspectors. I believe this has been done due to the fact that sprouters have been viewed as growing agricultural products indoors, and somehow their practices and facilities have been accepted. I have argued for 10 years that we must be viewed as food processors, and I knew that by not upgrading the industry to that level, given enough time, the industry would be in the state that it is in today (at a crisis level).

While there are many sprout companies who have been responsible and have taken steps to help make their product and the industry safe, they are now paying the price for those

who have ignored the problems in the industry. Because the industry has not had any mandatory guidelines that should have been implemented and enforced years ago, the industry is now facing what I feel are unreasonable requirements. Those companies that have endeavored to achieve a level of safe production, now have to pay the price because of those who have not. This includes everyone from the seed processors to the growers.

My concerns for the recommendations are as follows:

1. **Is it really necessary to test every crop?**

If the greatest potential problem is pathogens on the seed, then seed producers must be held accountable for treating and handling seeds as food products. This means not storing them in barns or warehouses that are not food grade facilities. This also means accountability from the time it is harvested as seed to the time it is delivered to the sprout grower. It should be mandatory at this time that all seed suppliers have HACCP programs in place, which would include adequate testing methods to insure sprout growers that they are reasonably sure the seed they are purchasing are free of pathogens. All seed producers and distributors for the sprouting industry should be inspected and regulated immediately.

Assuming the conditions in the above paragraph were in place. If a sprout grower is using the same seed lot for a long period of time, and they have implemented a regular testing program (say once a week), would that not be an adequate indicator that the seed is free of pathogens?

2. **Is it really necessary to view each drum as a batch, and not view multiple drums or an entire days harvest as a batch?**

I believe that by setting a volume of seed as being the criteria for a batch, and not a piece of equipment (ie. Drums), the same level of effective testing (as is recommended) could be achieved. If we set the limit at, say 200 lbs., it would not matter how many drums or trays were planted, the cut off point for the batch would be 200 lbs.

If that was divided into 4 drums, and test water was taken from each drum (100 ml), and a composite of the four drums was tested (400 ml), it should give us an adequate test if pathogens were present. My reasoning is this:

It is an accepted fact that the physical requirements for the growth of bacteria are ideal in the sprouting environment. Keeping this in mind, and the fact that the generation time for E. coli and *Salmonella* under these conditions is approximately 20 to 30 minutes, the exponential growth is tremendous. Even after a lag phase of 8 to10 hours, the growth after an additional 10 hours would be over 1 billion, and in 24 hours it would be a number trailed by 21 zeros. When taking 100 ml of water from a drum after 24 to 48

hours it would be nearly impossible not to detect E. coli or *Salmonella* using a valid testing method. I believe that we should have research done on this.

3. Is it necessary to take two samples from each batch?

While it is common practice for the scientific community to perform two tests side by side to insure accuracy, this should not be applied in the case of testing sprouts. My argument is that if regular testing is being done, say once a week or 2 batches each week, and the same seed lot is being used, the probability for not finding the presence of pathogens would be very remote.

It states in the recommendations that "as more effective treatments or other food safety controls are identified and implemented, the current recommendations.....may be changed." At this time all growers are placed in the same category, which is not fair. There are some with written SOP's, and written and documented HACCP and GMP programs.

If the FDA holds all sprout growers to the same standards, it will eliminate the bad growers. However, if the FDA makes the recommendations, and does not hold companies accountable, the companies who adhere to the regulations will be out of business. They would not be able to compete with people who do not comply with the regulations or recommendations. You will put the good growers out of business, and what you will have left are the bad growers.

Again thank you in advance for any considerations.

Sincerely,

F. J. Orkelair

Frank Orkelair
Sunrise Farms, Inc.

SUNRISE FARMS

FAX

Mailing Address: Sunrise Farms, Inc.
P.O. Box 212
Neenah, Wi 54957-0212

Shipping Address: Sunrise Farms, Inc.
1331 Gillingham Rd.
Neenah, Wi 54956

E- Mail: Sunrisewi@aol.com

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To: U.S. FOOD AND DRUG ADMINISTRATION - 202-205-4422

Attn: MICHELLE SMITH, PH.D.

Date: 11/12/99

From: Frank Crikelair / Sunrise Farms, Inc.

Phone: 920-722-7400 Fax: 920-722-7402

Re:

CROSS FILE SHEET

File Number: 99D 4488/C66

See File Number: 99D 4489/C67